REMARKS

Reconsideration and continuing examination of the above-identified application is respectfully requested in view of the amendments above and the discussion that follows.

Claims 1-24, 26-31, 36-37 and 43-50 have been cancelled. Claims 25, 32-35 and 38-42 have been amended. Claims 25, 32-35 and 38-42 are in the case and are before the Examiner.

I. The Amendments

Claim 25 has been amended to clarify that a claimed polypeptide is recombinantly expressed in a host cell and to limit the claimed sequences to those of KLH2. Specific support for the claim language can be found at least on pages 10 and 14 as well as in the originally filed Abstract. Specific support for the added subparagraph reciting sequence homology can be found at least at page 17 of the specification. The amendments to the remaining claims are designed to bring the claims into closer concert with the US form of claiming. No new matter has been added.

II. The Action

A. Objection to the Claims

Claims 24, 25, 32-35 and 38-42 were objected to for being dependent from a non-elected claim. It is believed that this basis for objection has been made moot by the present amendments.

B. Rejection Under 35 USC §112, First Paragraph

The Action noted a rejection under the first paragraph of Section 112. The claims were rejected as allegedly failing the "description requirement" of Section 112, first paragraph. The central issue of the rejection dealt with "fragments" of the recited polypeptides. It is believed that that basis for rejection is now moot in view of the present amendments.

C. First Rejection Under 35 USC §102

Claims 24 and 25 were rejected under 35 USC §102(b) as allegedly anticipated by the disclosures of Gebauer et al. (hereinafter Gebauer). The Action asserts that Gebauer teaches the isolation and separation of individual subunits from KLH2 and their molecular masses as assessed by SDS-PAGE, pointing specifically to Figure 4L of that paper that is said to show the isolation of the c subunit of KLH2 of *M. crenulata*. The Action also similarly rejected claims 24, 25, 32–35 and 38-42 upon the disclosures of Harris et al. (hereinafter Harris) that are said to teach the isolation of KLH1 and KLH2 from *M. crenulata*. These bases for rejection cannot be agreed with and are respectfully traversed together.

The Examiner's attention is invited to the enclosed Declaration of Jurgen Markl, one of the named inventors, that was filed for the companion application dealing with KLH1 (Serial No. 09/936,852). The inventor notes that no one has yet cloned any protein in cells of *M. crenulata*, that the pattern of glycosylation in KLH1 and KLH2 is unique and unusual. Papers published in refereed journals are enclosed with that Declaration that support his statements. See, for example, the Abstract of Kurokawa

et al., which includes Dr. Markl as a co-author, that ends with the statement:

> "[h]ence, our studies demonstrate that this marine mollusk glycoprotein is characterized by a unique oligosaccharide pattern comprising, in part, novel structural elements."

Dr Markl concludes in his Declaration that because there has been no known expression of any protein in cells of *Megathura crenulata* and because of the unique and unusual character of the glycosylation pattern of native KLH1 and KLH2 produced by *Megathura crenulata,* a presently claimed polypeptide cannot be the same as that obtained from *Megathura crenulata* and must therefore be novel over the art of record. Put differently, because no one knows how to express a protein in *Megathura crenulata* cells, those cells cannot be a "suitable host cell" as required by the claims. Still further, because the glycosylation pattern is unusual and unique, it will not be reproduced in any other known host cell. Again, therefore, the claimed subject matter is novel.

This basis for rejection should therefore be withdrawn.

D. Second Rejection Under 35 USC §102

Claims 38-42 were also rejected as allegedly anticipated, but here the anticipation was said to be by the disclosures of the 1995 Sigma Product Catalog, and particularly the teachings of a KLH composition from *M. crenulata* taught on page 520. This basis for rejection

cannot be agreed with and is respectfully traversed as discussed below.

It is respectfully submitted that as discussed above and in the enclosed Declaration, a recombinant polypeptide of the claims is novel over the material isolated from *M. crenulata*. *As such,* a pharmaceutical composition recited in claims 38-42 recites an isolated protein that was never available in the art before the present invention was made. It is thus submitted that this basis for rejection should be withdrawn.

III. Summary

Claims 1-24, 26-31, 36-37 and 43-50 have been cancelled. Claims 25, 32-35 and 38-42 have been amended. Each basis for rejection or objection has been dealt with and overcome or otherwise made moot.

It is believed that this application is in condition for allowance of all of the pending claims. An early notice to that effect is earnestly solicited.

No further fee or petition is believed to be necessary. However, should any further fee be needed, please charge our Deposit Account No. 23-0920, and deem this paper to be the required petition.

The Examiner is requested to phone the undersigned should any questions arise that can be dealt with over the phone to expedite this prosecution.

Respectfully submitted,

By _____
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Enclosure
Declaration and art
Form PTO-1449

CERTIFICATE OF MAILING

I hereby certify that this Reply and Amendment, with a Declaration by and inventor and art, and Form PTO-1449, are being deposited with the United States Postal Service with sufficient postage as First Class Mail in an envelope addressed to: MAIL STOP AMENDMENT, Commissioner for Patents, P.O. Box 1450, Alexandria, Virginia 22313-1450, on March 28, 2006.

By _____
Edward P. Gamson